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10/701,498	11/06/2003	Enok Tjotta	372407-342961	7642

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EXAMINER

STOCKTON, LAURA

ART UNIT PAPER NUMBER

1626

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/701,498

Applicant(s)

TJOTTA ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27 and 29-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/17/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

**Claims 27 and 29-33 are pending in the application.**

***Election/Restrictions***

During a telephone conversation with John W. Ryan on December 2, 2004, a provisional election was made with traverse to prosecute the invention of Group I, claims 27-33.

***Information Disclosure Statement***

The Information Disclosure Statement filed on June 17, 2005 has been considered by the Examiner.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicants' amendment to the claims. Therefore, arguments pertaining to these rejections will not be addressed. The following now apply.

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### ***Claim Objections***

Claim 30 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Since the definition of  $X_1$  has been amended to only represent oxygen, claim 30 does not further limit claim 27.

Claim 27 is objected to because of the following informalities: "pyrazolidine", in two occurrences, is misspelled.

Appropriate correction is required.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 and 29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The proviso at the end of claim 27 is confusing since  $X_1$  does not represent sulfur (per the current amendment to the claim), and therefore the condition in the proviso as to a 4-thiol group can never be met. In claim 27, it would appear that "acceptably" should be "acceptable".

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27 and 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by:

a) Negrevergue {U.S. Pat. 3,833,729} - see Example 1 in column 6 (CA Registry No. 35715-93-6);

b) Woodruff et al. {Australian Journal of Chemistry, (1975), 28(2), pages 421-426} - see, for example, the compound in Table I, seventh from the bottom (CA Registry No. 55228-15-4);

c) Giralaldi et al. {Gazzetta Chimica Italiana (1959), 89, pages 1373-1381} - see, for example, compounds V and Va on pages 1377 and 1380 (CA Registry Nos. 16860-43-8 and 112441-29-9);

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d) Hammond et al. {Journal of the Chemical Society, 1957, pages 1062-1067} - see the first compound listed in the Table on page 1063 and the second and third full paragraphs on page 1065;

e) Pala et al. {CA 77:28756, 1972} - see the product of CA Registry No. 37606-84-1 which has anti-inflammatory activity; or

f) Portoghesi et al. {Biochemical and Biophysical Research Communications (1975), 63(3), pages 748-755}- see the synthesis of 4-hydroxyoxyphenbutazone {CA Registry No. 55648-39-0} on page 751.

Each of the above cited references disclose at least one product that is embraced by the instant claimed invention.

### ***Response to Arguments***

Applicants' arguments filed June 17, 2005 have been considered. Applicants argue that: (1) the claims, as

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currently amended, require at least one pharmaceutically acceptable carrier or excipient and believe most of the rejections of anticipation are removed; and (2)  $R_1$  is restricted to hydrogen or an acyl group with up to six carbons thereby distancing the claims from Negrevergue.

In response, the instant claims, as amended, are anticipated by each of the above cited prior art references because each of the cited references disclose compounds embraced by instant formula I in a pharmaceutically acceptable carrier or excipient, such as water, ethanol, etc. (see Negrevergue, column 6, lines 24, 25 and 32-38). Also see page 7 of the instant specification. Further, Applicants are arguing a limitation that is not found in the instant claims. The  $R_1$  variable representing an acyl group is not limited to a certain number of carbons as Applicants have argued. Therefore, Negrevergue still anticipates the instant currently amended claimed invention.



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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Negrevergue {U.S. Pat. 3,833,729} and Vidal et al. {WO 97/35553}, each taken alone. Since the WO is in a non-English language, a U.S. equivalent, U.S. Pat. 6,551,360, will be referred to hereinafter.

***Determination of the scope and content of the prior art (MPEP***

***§2141.01)***

Applicants claim a pharmaceutical composition comprising a 1,2-diphenyl-3,5-dioxopyrazolidine compounds of formula (I) and a pharmaceutically acceptable carrier or excipient. Negrevergue (column 1, lines 17-55; and especially Example 1 in column 6,

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lines 24, 25 and 32-38) and Vidal et al. (formula (I) in column 1, lines 56-67; columns 2-3; column 7, lines 29-39; and especially column 3, lines 33-36 and 58-62) each teach 1,2-diphenyl-3,5-dioxopyrazolidine compounds that are either structurally the same as (see above 102 rejections) or structurally similar to the instant claimed compounds that are present in a pharmaceutically acceptable carrier or excipient such as water, ethanol, etc.

***Ascertainment of the difference between the prior art and the claims***

***(MPEP §2141.02)***

The difference between some of the compositions of the prior art and the compositions instantly claimed is that the compounds of formula (I) are generically described in the prior art.

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***Finding of prima facie obviousness--rational and motivation (MPEP  
§2142-2413)***

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compositions derives from the expectation that structurally similar compounds in the compositions would possess similar activity (e.g., an anti-inflammatory).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, inflammation. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

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### ***Response to Arguments***

Applicants' arguments filed June 17, 2005 have been considered. Applicants argue that: (1) the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness; and (2) to establish a *prima facie* case of obviousness, three basic criteria must be met which are some suggestion or motivation in either the references themselves or knowledge generally available to one skill in the art, reasonable expectation of success and the teaching or suggestion of all the claim limitations.

Applicants' arguments have been considered but have not been found persuasive. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Applicants claim a pharmaceutical composition comprising a 1,2-diphenyl-3,5-dioxopyrazolidine compounds of formula (I) and a pharmaceutically acceptable carrier or excipient. As stated above, each Negrevergue and Vidal et al. teach the same or similar compositions to that which is instantly claimed.

Further, each of the references either prepare a product that anticipates the instant claimed invention, Example 1 in column 6, lines 24, 25 and 32-38 in Negrevergue, or direct one skilled in the art toward products embraced by the instant claimed invention, see column 3, lines 33-36 and 58-62; and columns 7, lines 29-39 in Vidal et al. Each of the cited prior art teach that the compounds embraced by their genera are useful, such as for treating inflammation. Therefore,

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from the teaching and suggestion in the prior art references, one skilled in the art would have sufficient teaching and motivation to prepare additional products embraced by the prior art.

Applicants argue that: (1) consideration of all rebuttal arguments and evidence presented by Applicants is required; (2) the claimed compounds are exceptionally active and in particular are active in ways that are not anticipated by or suggested by any of the cited documents; and (3) Figures 1-5 demonstrate that 4-OH OPB is significantly more active against HIV virus than the closely related known compound OPB which is neither disclosed nor taught in Negrevergue or Vidal et al.

All of Applicants' rebuttal arguments and evidence has been considered but have not been found persuasive. Applicants are claiming a pharmaceutical composition, not a method of use. The instant claims embrace a multitude of products other than just 4-OH OPB. The

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instant claimed genus of pharmaceutical compositions are anticipated by prior art references (see above 102 rejections). Additionally, there is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. In re Dillon, 16 U.S.P.Q. 2d 1897, 1904 (Fed. Cir. 1990). For all the reasons given above, the instant claimed compositions would have been suggested to one skilled in the art and therefore would have been obvious to one skilled in the art.

### **Conclusion**

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

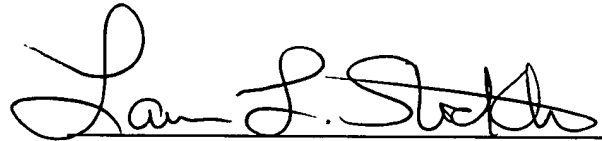
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

September 6, 2005